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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/694,293	10/23/2000	Stephen T. Kuehn	S16.12-0101	1653

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EXAMINER

NGUYEN, VI X

ART UNIT PAPER NUMBER

3731

DATE MAILED: 11/18/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/694,293

Applicant(s)

KUEHN ET AL.

Examiner

Victor X Nguyen

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18-33 is/are allowed.
- 6) ☒ Claim(s) 1-14 and 17 is/are rejected.
- 7) ☒ Claim(s) 15 and 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,12,14. 6) ☐ Other: _____

Art Unit: 3731

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-14 and 17 are rejected under 35 U.S.C. 102 (e) as being anticipated by Eberlin (U.S. 5,702,048).

Regarding claim 1, notes Eberlin figures 2, 3a and col. 5, lines 55-67 read on a surgical instrument comprising at-least one pair of arms (3), wherein the arms (3) sized and adapted for two adjacent leaflets; and wherein the arms (3) pivot from one orientation to a gripping position with ends of the pair arms being directed toward each other (figs 2,3a and figs 13-15).

Regarding claims 2 and 3, wherein the arms (3) flex to a core, wherein the surgical instrument has a gripping position, and wherein one of the arms (3) includes a projection for gripping a leaflet.

Regarding claims 4 ,5 and 13, notes Eberlin , fig. 2 read on a kit having a catheter (1), a fastener applicator (3), a leaflet fastener (4). The catheter (1) has a suitable dimension for deployment and insertion into a human heart. Furthermore, the pair arms (3) comprise the gripping elements.

Art Unit: 3731

Regarding claims 6, 7, wherein the opposed arms of a pair of arms comprise a pointed tip (6) and a clasp (not labeled) that engage each other in the gripping position. The arms (3) flex to a low position to fit within the catheter.

Regarding claims 8, 9, notes Eberlin, fig. 4, read on a kit, wherein the surgical instrument comprises a shaft and a sleeve (1) that slides over the shaft, wherein one member of the pair of arms slides along the shaft with the sleeve (1) engaging the sliding arms to constrain their movement along the shaft. The arms can slide along the shaft between a low position for fitting within the catheter (50).

Regarding claims 10-12, wherein the arms (3) pivot between a low position and an unconstrained extended position. The fastener applicator comprises a shaft, a latch (not labeled) and a bayonet fastener (labeled in col. 4, lines 14-20) holds the fastener on the shaft.

Regarding claims 14 and 17, wherein a surgical device includes a ring (4, figs 13-15) and an applicator, wherein the ring comprises two pointed shafts (figs 13, 14) and wherein the applicator can apply a force to the ring to deform the ring to bring the points of the shafts toward each other. The two pointed shafts (figs 13, 14) extend from a notch at which the ring (4) can be deformed to direct the pointed shafts toward each other.

Allowable Subject Matter

2. Claims 18-33 are allowed.

Claims 15 and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record disclose or suggest a heart valve repair

Art Unit: 3731

instrument includes a cap and a gripper, wherein the gripper includes a plurality of arms radiating from a pivot with each arms having a spike; and wherein the pivot is inserted within an opening in the cap to lock the arms in a collapsed gripping position.

Response to Arguments

3. Applicant's arguments filed 08/29/2003 have been fully considered but they are not persuasive. Applicant argues that the Eberlin '048 reference fails to show the arms do not fasten the adjacent leaflets. The examiner, respectfully, disagrees. The arms (3, fig 2 and figs 13-15) hold the staple (4) by its claws (6) are used to fasten the tissues of the vessels to be sutured. Regarding the intended use of the pair of arms to be adapted for fastening the adjacent leaflets, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the arms of Eberlin would have been capable of performing the use as claimed. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Regarding applicant's argument to rejection claim 14 that the Eberlin, item 4 is not a ring. The examiner, respectfully, disagrees. Item 4 in figures 13-14 is inherent feature that is capable of moving in or forming a ring, insofar as applicant has not recited the level or degree of the ring structure. Therefore, the claimed invention is not patentable over Eberlin's device.

Conclusion

Art Unit: 3731

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X Nguyen whose telephone number is (703) 305-4898. The examiner can normally be reached on M-F (8-4.30 P.M).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703) 746-3982.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Victor X Nguyen
Examiner
Art Unit 3731

Vn *VN*
November 14, 2003


MICHAEL J. MILANO
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